K020652 MAY 15 2002



Summary of Safety and Effectiveness

The Herniamesh T-Sling is substantially equivalent to the TVT (Tension-free Vaginal Tape) currently marketed by Ethicon Inc. and the BioSling™ – Bioabsorbable Polymer Sling & Surgical Mesh currently marketed by Prosurg Inc. / Injectx Inc. The 510 (k) "Substantial Equivalence" Decision-Making Process (detailed)" decision tree was utilized to make a determination of substantial equivalence (see Exhibit 1). The answers to the following questions lead to a determination of substantial equivalence.

1. Does the new device have the same indication statement?

Yes, the Herniamesh T-Sling has the same intended use as the legally marketed predicate devices listed above. All are pubourethral slings for the treatment of stress urinary incontinence (SUI) resulting from urethral hypermobility and/or intrinsic sphincter deficiency. Therefore, the Herniamesh T-Sling has the same intended use as the predicate devices and is considered to be "substantially equivalent."

2. Does the new device have same technological characteristics, e.g. design, materials, indication etc?

No, the Herniamesh T-Sling has different technological characteristics. However, the technological differences meet or exceed the functional requirements of surgical meshes compared to the predicate devices. Please refer to Table of Similarities and Differences / Substantial Equivalence to Predicate Devices.

3. Could the new technological characteristics affect safety and effectiveness?

Yes, the new technological characteristics could affect safety and effectiveness. The differences in safety and effectiveness meet or exceed the requirements of surgical meshes compared to predicate devices.

4. Do the new characteristics raise new types of safety or effectiveness questions?

No, the safety and effectiveness questions are not new and include issues such as materials, pore size, tensile strength, suture retention, and biocompatibility. Sufficient data has been provided in this premarket notification to address any new safety and efficacy questions. Additionally, there are a variety of other meshes currently on the market with different characteristics compared to the Herniamesh T-Sling or the predicate devices.

Summary of Safety and Effectiveness (continued)

5. Do accepted scientific methods exist for assessing the effects of the new characteristics?

Yes. The effects of the new characteristics of the Herniamesh T-Sling can be assessed by common methods utilized for surgical meshes. These include mechanical testing, scanning electron microscopy, biocompatibility and in vivo safety and effectiveness testing.

6. Are performance data available to assess the effects of the new characteristics?

Yes. These tests include mechanical testing, scanning electron microscopy, biocompatibility testing and in vivo testing.

7. Do performance data demonstrate equivalence?

Yes. The physical and mechanical characteristics of the Herniamesh T-Sling meet or exceed those of the predicate devices. Please refer to Table of Similarities and Differences / Substantial Equivalence to Predicate Devices.

Based on this information the Herniamesh T-Sling is determined to be substantially equivalent to the predicate devices.

**Table of Similarities and Differences / Substantial Equivalence to Predicate Devices (Continued)**

| Feature | Herniamesh T-Sling | Ethicon TVT | Injectx Inc BioSling™ |
|---|---|---|---|
| **Burst Strength** | 28.4 ($10^2$ Kpa) | 55 ± 3 ($10^2$ Kpa) | Substantially Equivalent |
| **Suture Retention (N)** | warp 43<br>weft 55<br>45° 52 | warp 52 ± 9<br>weft 51 ± 7<br>45° 57 ± 3 | Substantially Equivalent |
| **Pore Size** | 797.4µ & 228.3µ<br>Porosity 62.4% | Substantially Equivalent<br>Porosity 87% | Substantially Equivalent |
| **Tensile Strength** | warp 31.1<br>weft 33.1<br>45° 29.7 | warp 23 ± 6<br>weft 15 ± 5<br>45° 14 ± 5 | Substantially Equivalent |
| **Tissue Ingrowth** | Complete tissue incorporation of implant | Complete tissue incorporation of implant | Not Tested |

Note: Values for Prolene TVT were taken from the textbook: Prostheses and Abdominal Wall Hernias by Dr. Robert Bendavid (pages 197,200)

## Table of Similarities and Differences / Substantial Equivalence to Predicate Devices

| Feature | Herniamesh T-Sling | Ethicon TVT | Injectx Inc BioSling™ |
|---|---|---|---|
| **510(k) No.** | To be determined | K974098 | K010533 |
| **Classification** | Class II: Polymeric Surgical Mesh | Class II: Polymeric Surgical Mesh | Class II: Polymeric Surgical Mesh |
| **Indication** | Pubourethral sling for treatment of stress urinary incontinence (SUI) resulting from urethral hypermobility and/or intrinsic sphincter deficiency | Pubourethral sling for treatment of stress urinary incontinence (SUI) resulting from urethral hypermobility and/or intrinsic sphincter deficiency | Pubourethral sling for treatment of stress urinary incontinence (SUI) resulting from urethral hypermobility and/or intrinsic sphincter deficiency |
| **Product Design** | Pre-shaped Duel-component mesh Polypropylene and bioabsorbable polymer | Pre-shaped Polypropylene mesh | Pre-shaped bioabsorbable polymer and Surgical mesh |
| **Materials** | Polypropylene & Polydioxanone (Bioabsorbable Polymer) | Polypropylene | Bioabsorbable polyester Polymer |
| **Sterilization** | EtO | EtO | EtO |
| **Packaging** | Tyvek pouch with outer heat sealed foil pouch | PVC tray with Tyvek back | Substantially Equivalent |
| **Size** | 2cm x 15cm | 1.1cm x 45cm | Substantially Equivalent |

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 1 5 2002

Herniamesh USA, Inc.
c/o Ms. Lorena Trabucco
8 Orange Drive
Jericho, NY 11753

Re: K020652
Trade/Device Name: T-Sling
Regulation Number: 878.3300
Regulation Name: Surgical mesh
Regulatory Class: II
Product Code: FTL
Dated: February 21, 2002
Received: February 28, 2002

Dear Ms. Trabucco:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Attachment # 1

Indications for Use Form

510(k) Number: K020652

Device Name: T-Sling

Indications For Use:

The Herniamesh T-sling is a dual-component pubourethral sling for the treatment of stress urinary incontinence (SUI) resulting from urethral hypermobility and/or intrinsic sphincter deficiency.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ (per 21 CFR 801.109) OR Over-The-Counter Use (Optional Format 1-2-96)

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Miriam C. Provost

(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K020652